

## REMARKS

Claims 1, 3, 13, 15 and 17 has been amended. Claims 2, 13, 14 and 16 have been canceled without prejudice. Claims 4-6, 9, 10, 19-39, 41-48 have been withdrawn. Claims 1, 3, 7, 8, 11-12, 15, 17-18, and 40 remain before the Examiner for reconsideration.

In the Office Action dated April 7, 2006 the Examiner rejected Claims 1-3,7-8,11-18 and 40 under 35 U.S.C. 102(b) "as being anticipated by Ford et al (5,681,285)." Specifically, the Examiner asserted that:

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Ford discloses a control unit (80) a syringe (20), plunger (34), an interface module (10), syringe interface (clamping devices, see 8:10+), and drive member (see 8:19-20). See figures 1 and 5. The device also includes a motor (see 8:50+), a power source (84), one or more devices for controlling the drive member (keyboard 16 and internal memory with drug library) and a communication line (82). As shown in figure 5, the syringe interface module is adapted to be lain next to a patient or be placed in any suitable position since it is not fixed and physically separate (other than the communication line) to any other structures. The control unit includes a housing with circuitry (microprocessor among other circuitry). The control unit has a switch (on/off switch). The device also includes a battery. See 10:23+.

In response to the arguments filed by Applicant on January 10, 2006, the Examiner asserted that:

Applicant's argues the computer (80) in the Ford reference cannot read on a control unit comprising one or more devices for controlling a fluid injection. Additionally, applicant states that the computer (80) is used for loading a drug library and supplemental configuration data into the unit (10). However, the library and configuration data that the computer loads into the injection unit (10) is precisely what makes the computer a control unit. The computer (80) includes a memory, microprocessor, connector cable to the injector, and mouse. All these "devices" are used to download the drug and configuration data to the injector. The data determines the particulars of the fluid injection, e.g. rate. Therefore, the devices (memory, microprocessor, connector cable and mouse) control the fluid injection by transferring injection data to the unit (10) which is then used to actually perform the injection.

Applicants respectfully traverse the Examiner's rejection.

To assert anticipation under Section 102(b) the cases hold that the Examiner:

must show that each element of the claim in issue is found, either expressly described or under principles on inherency, in a single prior art reference, or, that the claimed invention was previously known or embodied in a single prior art device or practice.

Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. Denied, 465 U.S. 1026 (1984); Tyler Refrigeration v. Kysor Industrial Corp., 777 F.2d 687, 689, 227 USPQ 845, 846-47 (Fed. Cir. 1984) (judgment of anticipation reversed). "In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in the light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference." Lindemann, 730 F.2d at 1458, 221 USPQ at 485; Kalman, 713 F.2d at 771, 218 USPQ at 789.

"The test for determining if a reference anticipates a claim of a patent is whether the reference contains within its four corners adequate directions for the practice of the patent claim ... ." Kistler Instrument A.G. v. United States, 628 F.2d 1303, 1311, 203 USPQ 511, 519, aff'd, 211 USPQ 920 (Ct. Cl. 1980). The reference, whether foreign or domestic, patent or otherwise, must be construed strictly for what it "clearly and definitely discloses." Application of Boling, 292 F.2d 306, 310-11, 130 USPQ 161, 164 (CCPA 1961); Aluminum Co. of Am. v. Sperry Products, Inc., 285 F.2d 911, 922, 127 USPQ 394, 403 (6th Cir. 1960), cert. denied, 368 U.S. 890 (1961). A patent is not anticipated by a reference "unless the latter exhibits the invention in such full, clear and exact terms as to enable any person skilled in the art to practice it without making experiments." 285 F.2d at 922, 127 USPQ at 403.

Applicants respectfully assert that, under the appropriate standard as set forth above, Ford does not anticipate the present invention. Unlike the present invention, Ford does not disclose or suggest that computer 80 thereof is a control unit including one or

more devices for controlling a fluid injection or, in other words, that computer 80 is adapted to transmit a control signal to a syringe interface for controlling a drive member during fluid delivery. Applicants have amended independent claim 1 to more clearly set forth that the control unit of the present invention is adapted to supply a control signal to the motor of the syringe interface module during fluid delivery. Applicants respectfully assert that the limitations added to claim 1 do not raise any new issues requiring further search, examination or consideration as such claim limitation are incorporated from original claims 13, 14 and 16. Claims 13, 14 and 16 have been canceled.

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Claim 1 thus sets forth, *inter alia*, a control unit comprising control circuitry adapted to transmit a control signal to the motor of the syringe interface module to control the fluid injection during the fluid injection. To the contrary, the Ford patent discloses that personal computer 80 thereof is used for electronically loading a customized drug library and supplemental configuration data into the infusion pump 10. (Col. 10, lines 64-67 to Col. 11, line 1.) Further, pump 10 can download pump events to personal computer 80 to allow clinicians to perform automated record keeping relative to drug infusion history for a specific patient, and to collect pump utilization information. (Col. 6, lines 48-52.) The Ford patent explains that “[a] significant advantage of the present invention is that it enables clinicians to easily customize their drug infusion pumps by electronically injecting customized drug libraries and configuration data into them.” (Col. 6, lines 23-29.)

The Ford patent thus merely discloses that personal computer 80 can be connected to the pump 10 to upload or download data as follows: (1) update the drug libraries and configuration information in the pump 10 and to (2) download pump events from the pump 10 for patient drug infusion history and pump usage information. Contrary to the Examiner’s assertion, the library and configuration data that personal computer 80 of Ford loads into injection unit 10 thereof is NOT precisely what makes personal computer 80 of Ford a control unit. Once again, a control unit under the common definition thereof and as claimed in the present invention is adapted to transmit a control signal to control the fluid injection as set forth above.

Contrary to the presently claimed invention, Ford discloses that the control devices for pump 10 thereof are included within the pump 10 itself, and not within personal computer 80 thereof. Specifically, the Ford patent discloses that pump 10 thereof includes a drive control system using pulse-width modulation, a DC gear motor, motor drive circuitry, a proportional integral-differential control algorithm, a master microprocessor 40, and a slave microprocessor 42. (Col. 8, lines 50-67.) Further, Ford patent discloses that “[m]aster processor 40 is primarily dedicated to operating the pump motor through a motor control module 53.” (Col. 9, lines 1-3.) Clearly, and contrary to the present invention, Ford discloses that the control unit for pump 10 thereof resides within pump 10 itself, and not within personal computer 80. Thus, there is no disclosure or suggestion in the Ford patent that personal computer 80 of Ford is a “control unit” as set forth in claim 1.

In view of the above remarks, applicants respectfully requests that the Examiner, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,  
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